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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HUH, BENJAMIN

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/031,627	Applicant(s) KENDALL ET AL.	
	Examiner Benjamin Huh	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 and 55 is/are pending in the application.
- 4a) Of the above claim(s) 8, 35 and 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-34, 36-37, and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II and species A (fig. 5) in the reply filed on 8/25/05 is acknowledged. Claims 8, 35, & 38-41 are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-12, 14-25, 26, 27, 29-32, 34, 36, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by BELLHOUSE et al. (US Patent No. 5,630,796). Bellhouse discloses a needless injection device and method of using the device including a rupturing membrane closure means (col. 8, ll. 1-5), substantially constant diameter driver chamber (upstream of rupturable membrane 34), substantially constant diameter duct section connected to driver chamber to receive gas therefrom, (constant diameter is within distal section of duct section, fig. 1), dose of particles P upstream of closure means 34, fig. 8, divergently contoured nozzle 38 (downstream of duct) through which a quasi-steady flow travels, whereby the device generates shock waves and reflection waves upon rupturing the membrane. A bleed hole is disclosed to provide the pathway from pressurized gas to the driver chamber and a bleed valve is understood in the art to be of small size that it would substantially decouple the driver chamber with

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pressurized gas source (col. 4, line 62 - col. 5, line 2). Nozzle areas are chosen with respect to driver chamber pressure to be correctly expanded (col. 5, ll. 22-33; col. 5, ll. 60-65; col. 6, ll. 5-7). Different gases are selected to give different velocities (col. 6, ll. 5-7).

Some limitations recited in the claims are considered inherent. Establishing quasi-steady flow upstream of shock waves, claims 1, 5, 20, entraining and accelerating particles in quasi-steady flow, claims 1, 20, initiating a starting process when shock wave reaches duct section end, claim 2, 21, producing a secondary shock wave behind primary shock wave, claim 4, uniform velocity distribution over a cross-section, claims 11, 32, no oblique shocks waves within the divergent nozzle, claims 12, 31, initiating (u-a) wave at duct end, claim 14, quasi-steady flow upstream of (u-a) wave, claim 15, expansion wave traveling upstream of membrane closure means, claim 16, and terminating quasi-steady flow when reflected expansion wave passes out of the device, claim 18 are considered inherent functions resulting from the generation of shock waves by rupturing a membrane at the downstream end of a driver chamber with a constant diameter duct section, and divergent nozzle.

The prior art discloses the same or similar structure recited in the claims and described in the specification with respect to fig. 5 and this similarity is the basis that the prior art device will inherently function as the claimed device and produce the associated waves and effects in use with shock waves. If Applicant argues that these claimed functions are not inherent Applicant should submit evidence that the prior art

devices do not inherently possess these characteristics. See MPEP 2112, 2112.01, 2112.02.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9-18, 20-34, 36, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over HEINZEN (WO 97/47730) in view of BELLHOUSE (US Patent No. 5,899,880). Heinzen discloses a needless injection device (Fig. 1) and method of using the device including a rupturing membrane 18 closure means, driver chamber 13, constant diameter duct section 22, dose of particles in region of closure means 14, divergently contoured nozzle 24 through which flow travels, whereby the device generates an accelerated gas stream upon rupturing the membrane, and determining nozzle areas in accordance with pressures used in the device. The device is considered correctly expanded because the nozzle areas are chosen to correspond to the desired gas flow (pg. 10, line 3 - pg. 12, line 14).

Re claims 13 and 33 Heinzen discloses the claimed invention as per fig. 1, and discloses spacers 60 in the embodiment shown in figs. 4 and 5. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the embodiment shown in fig. 1 with the spacers seen in figs. 4 and 5 and described at pg.

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21, ll. 9-28 in order to allow for reproducible results between subsequent deliveries, as described by Heinzen.

Re claims 6 and 27 Heinzen discloses the claimed invention except for placing the particles in an initial position upstream of the closure means. Bellhouse '880 teaches placing the particles in an initial position of closure means 34 which rupture to allow the particles to be injected (figs. 8, 8a, col. 9, line 60 - col. 10, line 8; col. 11, ll. 9-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Bellhouse '880 in the device and method of Heinzen in order to provide a replaceable capsule containing the particles to be injected.

Although disclosing releasing a pulse of compressed gas to achieve significant speed of injection, Heinzen does not disclose the gas flow as a shock wave, quasi-steady gas flows, or a bleed hole to de-couple the driver from gaseous fluid source. See figs. 1, 2a-c; pg.4, ll. 4-29; pg. 9, line 22 - pg. 10, line 2; pg. 10, line 28 - pg. 11, line 22; pg. 12, ll. 5-11; pg. 12, ll. 12-36. Bellhouse teaches the use of high gas pressure to generate a shock wave to achieve velocities for particle injection and a bleed hole to couple the driver chamber to a pressure source (col. 2, ll. 8-25; col. 3, ll. 58-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Bellhouse '880 in the device and method of Heinzen to achieve different gas pressures and velocities to achieve different depths of particle penetration.

Some limitations recited in the claims are considered inherent. Establishing quasi-steady flow upstream of shock waves, claims 1, 5, 20, entraining and accelerating particles in quasi-steady flow, claims 1, 20, initiating a starting process when shock

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wave reaches duct section end, claim 2, 21, producing a secondary shock wave behind primary shock wave, claim 4, uniform velocity distribution over a cross-section, claims 11, 32, no oblique shocks waves within the divergent nozzle, claims 12, 31, initiating (u-a) wave at duct end, claim 14, quasi-steady flow upstream of (u-a) wave, claim 15, expansion wave traveling upstream of membrane closure means, claim 16, and terminating quasi-steady flow when reflected expansion wave passes out of the device, claim 18 are considered inherent functions resulting from the generation of shock waves by rupturing a membrane at the downstream end of a driver chamber with a constant diameter duct section, and divergent nozzle. With regards to using a spacer, as a result of spacing the device end from the target tissue with a divergent nozzle it is inherent to create normal shock wave at divergent nozzle exit and to decelerate particles in normal shock wave having generally radially uniform velocity, claims 13, 33, due to the spacing. The prior art discloses a space similar to the space recited in the claims.

The prior art discloses the same or similar structure recited in the claims and described in the specification with respect to fig. 5 and this similarity is the basis that the prior art device will inherently function as the claimed device and produce the associated waves and effects in use with shock waves. If Applicant argues that these claimed functions are not inherent Applicant should submit evidence that the prior art devices do not inherently possess these characteristics. See MPEP 2112, 2112.01, 2112.02.

Claims 19 and 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over HEINZEN and BELLHOUSE '880 as applied to claims 1 and 36 above, and further in

view of BELLHOUSE '478. Heinzen and Bellhouse '880 teach the claimed invention except for scoring the rupturable membrane and choosing different gas species to control particle velocities. Bellhouse '478 teaches scoring a rupturable membrane in order to limit shedding fragments (col. 8, ll. 52-55) and selecting different gases to give different velocities (col. 6, ll. 15-44; col. 7, line 44 - col. 9, line 20). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Bellhouse '478 in the device of Heinzen and Bellhouse '880 in order to facilitate rupturing the membrane preventing unwanted material from traveling to the target site and to achieve different penetration depths with different gas velocities.

Response to Arguments

Applicant's arguments filed 5/30/06 have been fully considered but they are not persuasive.

Applicant argues that Bellhouse does not produce a quasi-steady flow upstream of a shockwave that entrains and accelerates substantially all of the dose of particles within the substantially quasi-steady flow, the examiner disagrees. The applicant acknowledges in the specification of the instant application on page 1 that Bellhouse according to line 23-24 "delivers pharmaceutical particles entrained in a supersonic gas flow" and on page 2 lines 3-6 "particles to be delivered are disposed adjacent to the rupturable membrane and are delivered using an energizing means which applies a gaseous pressure to the upstream side of the membrane sufficient to rupture the membrane and produce a supersonic gas flow (containing the pharmaceutical particles)

through the nozzle for delivery from the downstream end thereof". Also, it is noted that since the prior art contains all of the structural limitations of the claims that the device would inherently perform the same as the instant application or that the applicant has left out essential subject matter in the claims. It is also noted that according to page 15 of the rejections under 102 in the remarks filed, the applicant states that "the office action acknowledges that the establishing a quasi-steady flow upstream of a shock wave as well as entraining and accelerating particles in the quasi-steady flow is not taught by Bellhouse", the examiner does not see where the previous office action acknowledged that point. The arguments are found not to be persuasive and the examiner suggests that the applicant submit data that the referenced prior art can not perform the same capabilities of the instant application and to add more limitations and details concerning the flow.

Applicant argues that Heinzen does not disclose all the limitations of the claims; the examiner would like to point out that the Heinzen reference was utilized as a 103 reference in combination of Bellhouse ('880) and wherein the claims are rejected by Heinzen in view of Bellhouse and with respect to the skill of one of ordinary skill in the art. Also, it is noted that since the prior art contains all of the structural limitations of the claims so that the device would inherently perform the same as the instant application or that the applicant has left out essential subject matter in the claims.

The arguments with respect to claims 19 & 37 refer the examiner to the arguments concerning claim 20 since claims 19 and 37 depend on the limitations of

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claim 20, therefore, the applicant is referred to the arguments made above concerning claim 20(Bellhouse 102 & Heinzen in view of Bellhouse 103).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bellhouse (US Patent No. 6,010,478) and Bellhouse WO 96/12513 show needless injectors with rupturable membranes to create a shock wave to carry particles for injection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

A handwritten signature in black ink, reading "Kevin C. Sirmons". The signature is written in a cursive, flowing style with a large initial 'K'.